

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 November 2001 (29.11.2001)

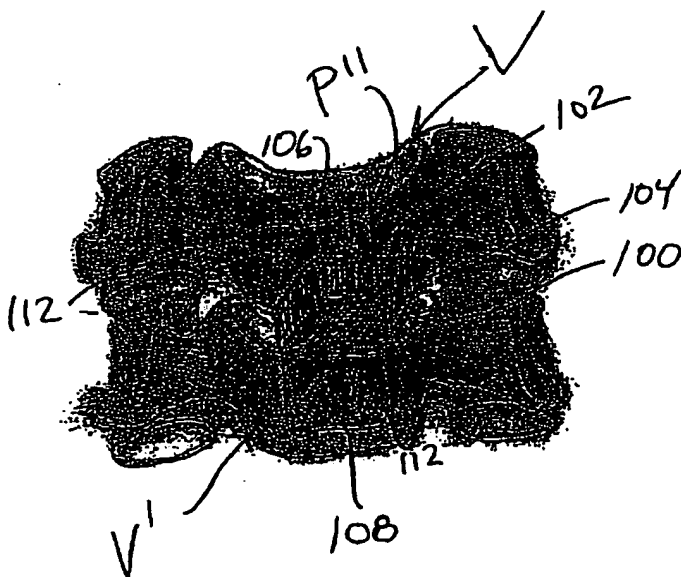
PCT

(10) International Publication Number
WO 01/89428 A2

- (51) International Patent Classification⁷: A61F 2/44
- (21) International Application Number: PCT/CA01/00739
- (22) International Filing Date: 25 May 2001 (25.05.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/206,810 25 May 2000 (25.05.2000) US
60/264,309 29 January 2001 (29.01.2001) US
- (71) Applicant (for all designated States except MG): SEVRAIN, Lionel, C. [FR/US]; 5 Hilldale Road, Plymouth, MA 02360 (US).
- (71) Applicant (for MG only): SOFIA, Michel [CA/CA]; Swabey Ogilvy Renault, 1981 McGill College Avenue, Suite 1600, Montreal, Quebec H3A 2Y3 (CA).
- (74) Agents: SOFIA, Michel et al.; Swabey Ogilvy Renault, Suite 1600, 1981 McGill College Avenue, Montreal, Quebec H3A 2Y3 (CA).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: INTER-VERTEBRAL DISC PROSTHESIS FOR RACHIS THROUGH ANTERIOR SURGERY THEREOF



(57) Abstract: A disc prosthesis (P, P') for use on a pair of adjacent vertebrae (V, V') comprises upper and lower plates (10/12, 30/32, 106/108) adapted to be mounted respectively to adjacent upper and lower vertebrae (V, V') typically using screws that extend through holes defined in the plates (10/12, 30/32, 106/108) and into the vertebrae (V, V'), a joint mechanism (16, 36, 100) linking the upper and lower plates, and a damping system (26, 104). The joint mechanism and the damping system are adapted to allow for biased relative movements between the upper and lower vertebrae (V, V'). For instance, the joint mechanism comprises a substantially V-shaped joint (16) extending at least partly in an intersomatic space (S) defined between the upper and lower vertebrae (V, V') and in a substantially axial plane thereof. The V-shaped joint (16) has a pair of arms (18, 20) adapted to pivot relative to each other thereby allowing for at least one of an extension and a contraction movement between the upper and lower

vertebrae (V, V'), with the damping system (26) being adapted to act on the V-shaped joint (16). Alternatively, the joint mechanism comprises an anterior guillotine-type, or cigar-cutter, joint (36) having engaged upper and lower members (30, 32) adapted for sliding relative movements therebetween along an axial orientation of the vertebrae (V, V'), and with the damping system being adapted to act on the guillotine-type joint (36). The joint mechanism can also include a flexible deformable jacket (100) lodged in the intersomatic space (S) and defining a chamber (102) adapted to receive therein a dampening fluid, such as a hydrogel (104).

BEST AVAILABLE COPY

WO 01/89428 A2

Notice of References Cited

Application/Control No.

10/160,407

Applicant(s)/Patent Under
Reexamination
MICHELSON, GARY K.

Examiner

Pedro Philogene

Art Unit

3732

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,616,142	04-1997	Yuan et al.	606/61
	B	US-5,672,177	09-1997	Seldin, Edward B.	606/71
*	C	US-6,402,756 B1	06-2002	Ralph et al.	606/71
	D	US-6,217,580 B1	04-2001	Levin, L. Scott	606/71
	E	US-6,152,927	11-2000	Farris et al.	606/69
*	F	US-6,306,136 B1	10-2001	Bacelli, Christian	606/61
	G	US-5,167,665	12-1992	McKinney, William W.	606/75
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/160,407	06/04/2002	Gary K. Michelson	101.0114-00000	2495
22882	7590	03/11/2004	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			PHILOGENE, PEDRO	
			ART UNIT	PAPER NUMBER

3732

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/160,407	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Pedro Philogene	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-240 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-240 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03</u> | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-240 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-228 of copending Application No. 10/160086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between these two sets of claims is that in the '086 application the at least one bone screw lock adapted to lock to the plate at least a single bone screw instead of the two bone screws as claimed in the '407 application. The question then becomes – Does the omission of the second bone screw being locked in the claim of the '086 application constitute an obvious expedient to one of ordinary skill in the art?

It is well settled that the omission of an element and its function is an obvious expedient if the remaining elements perform the same function as before. *In re Karlson*, 136 USPQ 184 (CCPA 1963).

Therefore, the omission of an element whose function is not needed would be obvious to one of ordinary skill in the art. Furthermore, the claims of the '407 application and the claims of '086 application both cover all the elements of the plate system – that is the first and second plate segments the lower surface, the bone screw receiving holes, the fastener, the at least one bone screw lock and the instrument. Thus, the controlling fact is that patent protection for the plate system, fully disclosed in and covered by the claims of the '407 application, would be extended by the allowance of the claims in the '086 application. And nothing prevented applicant from presenting the claims in the '086 application for examination during the prosecution of the issued patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-240 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-143 of copending Application No. 10/160059. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 1-240 of '407 application are to be found in claims 1-243 of '059 application. The difference between claims 1-240 of the 407 application and claims 1-143 of the '059 application lies in the fact that the '059 application claims include many more elements and is thus much more specific. Thus the invention of claims 1-143 of '059 application is in effect a "species" of the "generic" invention of claims 1-240 of '407 application. It has been held that the generic invention is "anticipated" by the "soecies".

Art Unit: 3732

See *in re Goodman*, 29 USPQ2d 2010 (Fed.Cir. 1993). Since claims 1-240 of the '407 application are anticipated by claims 1-143 of the '059 application, they are not patentably distinct from claims 1-143.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-240 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-203 of copending Application No. 10/160,062 in view of McKinney (5,167,665). It is noted that the '062 application teaches all the elements, except for a fastener being non-detachably attached to at least one of the first and second plate segment so as prevent complete uncoupling of the segments; as claimed by applicant. However, in a similar art, McKinney evidences the use of a fastener with a double head to hold two objects together and prevent them from uncoupling, the fastener is set after a force is applied on the fastener.

Therefore, given the teaching of McKinney, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fastener of '062 application with the fastener, as taught by McKinney, to have a fastener that is no-detachably attached to the plate segments so as to prevent complete uncoupling of the segments.

This is a provisional obviousness-type double patenting rejection.

Claims 1-240 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-260 of

Art Unit: 3732

compending Application No. 10/160,247 in view of McKinney (5,167,665). It is noted that the '247 application teaches all the elements, except for a fastener being non-detachably attached to at least one of the first and second plate segment so as prevent complete uncoupling of the segments; as claimed by applicant. However, in a similar art, McKinney evidences the use of a fastener with a double head to hold two objects together and prevent them from uncoupling, the fastener is set after a force is applied on the fastener.

Therefore, given the teaching of Mckinney, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fastener of '247 application with the fastener, as taught by McKinney, to have a fastener that is no-detachably attached to the plate segments so as to prevent complete uncoupling of the segments.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-117,183-240 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli (6,306,136) in view of Mckinney (5,167,665) in view of Farris et al. (6,152,927).

With respect to claims 1, 183, Baccelli discloses all the elements first and second plate segments (10) a lower surface being concave, as set forth in column 5, lines 1-8; at least one bone screw receiving hole (111) at least one fastener (30).

It is noted that Baccelli teaches all the elements, except for a fastener being non-detachably attached to at least one of the first and second plate segment so as prevent complete uncoupling of the segments; as claimed by applicant. However, in a similar art, McKinney evidences the use of a fastener with a double head to hold two objects together and prevent them from uncoupling, the fastener is set after a force is applied on the fastener.

Therefore, given the teaching of McKinney, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fastener of '247 application with the fastener, as taught by McKinney, to have a fastener that is no-detachably attached to the plate segments so as to prevent complete uncoupling of the segments.

Although Baccelli teaches of a bone screw lock, it is noted that Baccelli did not teach of a bone screw lock adapted to lock at least two bone screws inserted in the bone screw receiving holes respectively; as claimed by applicant. However, in a similar art, Farris et al evidence the use of a bone screw lock capable of locking one or more bone screws within a respective screw hole.

Therefore, given the teaching of Farris et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the locking

assembly of Baccelli, as taught by Farris et al., to have a bone screw lock capable of locking one or more bone screws within a respective screw hole.

With respect to claims 2-75, 184-240, the above combination of references teaches all the limitations, as set forth.

With respect to claims 76-117, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Claims 118-182 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli (6,306,136) in view of McKinney (5,167,665) in view of Farris et al. (6,152,927) in view of Levin (6,217,580).

With respect to claim 118, it is noted that the above combination of references teaches all the limitations, except for an instrument configured to cooperatively engage the fastener and the first and second plate segments; as claimed by applicant.

However, in a similar art, Levin evidences the use of an instrument that engages the first and second plate segments, and pull them closer together.

Therefore, given the teaching of Levin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the instrument of Levin in the device of Baccelli/McKinney/Farris to have an instrument that engages the first and second plate segments and pull them closer together.

With respect to claims 119-182, the above combination of references teaches all the limitations, as set forth.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,402,756	06-2002	Ralph et al.
5,672,177	09-1997	Seldin
5,616,142	04-1997	Yuan et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
March 9, 2004

PEDRO PHILOGENE
PRIMARY EXAMINER

MARTIN & FERRARO, LLP
1925 Century Park East, 17th Floor
Los Angeles, California 90067

Telephone
(310) 286-9800

Facsimile
(310) 286-2795

FACSIMILE TRANSMITTAL

TO:

Name: Mail Stop AMENDMENT
Art Unit 3732/Examiner Pedro Philogene

Firm: U.S. Patent & Trademark Office

Fax No.: 703-872-9306

Subject: U.S. Patent Application No. 10/160,407

Gary K. Michelson

Filed: June 4, 2002

**DYNAMIC MULTILOCK ANTERIOR CERVICAL
PLATE SYSTEM HAVING NON-DETACHABLY
FASTENED AND MOVEABLE SEGMENTS,
INSTRUMENTATION, AND METHOD FOR
INSTALLATION THEREOF**

Attorney Docket No. 101.0114-00000

Customer No. 22882

Confirmation No.: 2495

FROM:

Name: Amedeo F. Ferraro

Phone No.: 310-286-9800

No. of Pages (including this): 52

Date: September 13, 2004

Confirmation Copy to Follow: YES

Courtesy Copy of Information
Disclosure Statement and Form PTO-
1449 with copies of the 9 documents
cited therein

Message:**CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8**

I hereby certify that the attached Transmittal Form (in duplicate; \$1,130.00 total to cover the \$950 three-month extension fee and \$180 IDS fee is to be charged to Deposit Account No. 50-1066), Reply to Office Action with Exhibits A-C, and Information Disclosure Statement Under 37 C.F.R. § 1.97(c) with Form PTO-1449 are being facsimile transmitted to the U.S. Patent and Trademark Office on September 13, 2004.

Sandra L. Blackmon

If there is a problem with this transmission please call Sandy Blackmon at 330-877-1202 or the sender at the number above.

The information contained in this facsimile message is privileged and confidential information intended only for the use of the addressee listed above. If you are not the intended recipient or the employee or agent responsible to deliver this message to the intended recipient, please do not use this transmission in any way, but contact the sender by telephone.

FORM PTO-1083

Attorney Docket No.: 101.0114-00000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson

Serial No: 10/160,407

Filed: June 4, 2002

For: DYNAMIC MULTILOCK ANTERIOR
CERVICAL PLATE SYSTEM HAVING
NON-DETACHABLY FASTENED
AND MOVEABLE SEGMENTS,
INSTRUMENTATION, AND METHOD
FOR INSTALLATION THEREOF

Confirmation No.: 2495

Art Unit: 3732

Examiner: Pedro Philogene

RECEIVED
CENTRAL FAX CENTER
SEP 13 2004Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a reply to the Office Action dated March 11, 2004 in the above-identified application.

- ☐ No additional fee is required.
- ☒ Applicant hereby requests a three-month extension of time to respond to the above Office Action.
- ☒ An Information Disclosure Statement Under 37 C.F.R. § 1.97(c) with Form PTO-1449 and 9 documents are enclosed.
- ☒ A fee in the total amount of \$1,130.00 to cover the \$950 three-month extension and \$180 IDS is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. A copy of this sheet is enclosed.
- ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
- ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: September 13, 2004

By: Amedeo F. Ferraro
Registration No. 37,1291557 Lake O'Pines Street, NE
Hartsville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030

PATENT
Attorney Docket No. 101.0114-00000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Gary K. Michelson)
Serial No.: 10/160,407) Confirmation No.: 2495
Filed: June 4, 2002)
For: DYNAMIC MULTILOCK ANTERIOR)
CERVICAL PLATE SYSTEM HAVING)
NON-DETACHABLY FASTENED AND) Group Art Unit: 3732
MOVEABLE SEGMENTS,) Examiner: P. Philogene
INSTRUMENTATION, AND METHOD)
FOR INSTALLATION THEREOF)

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TO OFFICE ACTION

In reply to the Office Action dated March 11, 2004, the period for reply having been extended for three (3) months by a request for extension and fee payment filed concurrently herewith, the following remarks are submitted:

In the Office Action Summary, the disposition of the claims did not include claims 241-244 as being pending in the application and the Examiner did not address dependent claims 241-244 in the body of the Office Action. The present application was originally filed with claims 1-244. Applicant respectfully submits that in the event that the Examiner rejects claims 241-244 in the next action, that rejection must be non-final because Applicant has not been given an opportunity to address any rejection of these claims in the first instance.

Reply to OA 9-13-04.doc

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

I. Provisional obviousness-type double patenting rejections.

The Examiner provisionally rejected claims 1-240 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-228 of copending Application No. 10/160,086 (the "'086 application"); over claims 1-143 of copending Application No. 10/160,059 (the "'059 application"); over claims 1-203 of copending Application No. 10/160,062 (the "'062 application") in view of U.S. Patent No. 5,167,665 to McKinney ("McKinney"); and over claims 1-260 of copending Application No. 10/160,247 (the "'247 application") in view of McKinney.

A. '086, '062, and '247 applications are directed to patentably distinct subject matter.

Applicant respectfully traverses the Examiner's provisional obviousness-type double patenting rejection in view of the '086, '062, and '247 applications. Applicant submits that the subject matter of each of these applications is patentably distinct from one another and from the present application as set forth in the Restriction Requirement dated March 26, 2004 issued in the '059 application (the "'059 Restriction Requirement") and the Restriction Requirement set forth in the Office Action dated September 8, 2004 in the '059 application (the "'059 Office Action"). Attached hereto as Exhibits A, B, and C are copies of the '059 Restriction Requirement, Figs. 1A-1D of the drawings from the '059 application, and the '059 Office Action, respectively.

The '059 Office Action includes a further restriction requirement that restricts the claims to a first group directed to "a plate adapted to be applied to the anterior human cervical spine" and to a second group directed to "a method for stabilizing at least two adjacent vertebral bodies." The Examiner of the '059 application has determined that the claims directed to the plate are patentably distinct from the claims directed to the method. In response to the further restriction, Applicant elected the claims directed to the plate in the '059 application.

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

The '059 Restriction Requirement clearly identifies the subject matter of each of the '062, '086, and '247 applications, and the present application as being separate species A, B, C, and D, respectively.

Species A of the '059 Restriction Requirement includes the subject matter of the '062 application, which is generally directed to a plate having a lock for locking only a single bone screw ("single-lock") and a plate fastener that is detachable. (See, e.g., Exhibit B, Fig. 1A).

Species B of the '059 Restriction Requirement includes the subject matter of the '086 application, which is generally directed to a plate having a single-lock and a plate fastener that is non-detachably attached. (See, e.g., Exhibit B, Fig. 1B).

Species C of the '059 Restriction Requirement includes the subject matter of the '247 application, which is generally directed to a plate having a lock for locking at least two bone screws ("multi-lock") and a plate fastener that is detachable. (See, e.g., Exhibit B, Fig. 1C).

Species D of the '059 Restriction Requirement includes the subject matter of the present application, which is generally directed to a plate having a multi-lock and a plate fastener that is non-detachably attached. (See, e.g., Exhibit B, Fig. 1D). Accordingly, Applicant submits that the claimed subject matter of the present application and of each of the '086, '062, and '247 applications are each patentably distinct from one another as recognized by the Office in the '059 Restriction Requirement. Applicant respectfully requests the Examiner to withdraw the provisional obviousness-type double patenting rejections of claims 1-240 in view of the '059 Restriction Requirement.

B. The present application is patentably distinct from the '086 application.

Moreover, Applicant respectfully disagrees with the rationale provided by the Examiner in the Office Action to support each of the provisional obviousness-type double patenting rejections. In the provisional obviousness-type double patenting rejection of the present application in view of the '086 application, Applicant respectfully disagrees with the Examiner's contention that "patent protection for the plate system,

Application No. 10/180,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

fully disclosed in and covered by the claims of the '407 application, would be extended by the allowance of the claims in the '086 application." (Office Action, page 3, paragraph 1). The present application and the '086 application were both filed on June 4, 2002. Accordingly, both applications will expire on the same day, subject to any patent term adjustment, if applicable.

Applicant submits that it would not be obvious to replace individual single-locks with a multi-lock. A plurality of single-locks, each adapted to lock only a single bone screw, permits bone screws to be positioned and locked in areas of the plate that may not be suitable for use with a multi-lock adapted to lock at least two bone screws. Depending upon the surgical environment, certain situations and anatomical constraints may limit the arrangement of bone screws relative to the plate in a manner that may not be accessible by one locking element for locking more than one bone screw at a time. The Examiner has not provided any motivation to support his contention that it would have been obvious to replace a plurality of single-locks with a multi-lock. Accordingly, Applicant submits that the subject matter of the present application is patentably distinct from the subject matter of the '086 application.

C. The present application is patentably distinct from the '062 and '247 applications.

For both of the provisional obviousness-type double patenting rejections of the present application in view of each of the '062 and '247 applications, Applicant submits that the proposed combination of McKinney with the subject matter of each of the '062 and '247 applications is untenable. The claims of the '062 and '247 applications each recite a fastener that is "detachably attached to at least one of said first and second plate segments so as to permit assembly of said first and second plate segments by the surgeon and complete uncoupling of said first and second plate segments relative to one another." McKinney teaches a rivet 11 having a head 33, a shank 25, and an inner head 49. (McKinney, col. 3, lines 40-43; col. 4, lines 43-45; and Fig. 1). The rivet is configured so that "the object 13 is clamped to the cortex 53 of the bone 17 by the two

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

heads 33, 49 of the rivet." (McKinney, col. 4, lines 57-59; Fig. 1) The purpose of head 33 is to hold the plate while head 49 is "expanded against the cortex so as to secure the rivet means against the bone." (McKinney, col. 2, lines 15-17). Replacing the fastener recited in the claims of the '062 and '247 applications with the bone rivet taught by McKinney would render the plates of the '062 and '247 applications unsatisfactory for their intended purpose because the bone rivet taught by McKinney is not adapted for securing two plate segments to one another. Moreover, McKinney does not teach or suggest a fastener having a position that "facilitates movement...toward" and "resists movement... away" of the plate segments along the longitudinal axis of the plate as recited in independent claim 1 of the present application. The use of the McKinney rivet in combination with the claims of each of the '062 and '247 applications would not result in the claimed invention.

Additionally, the plates recited in the '062 and '247 applications have detachable fasteners that provide the advantages of using disassembled plate segments within a surgical wound in instances where the use of a pre-assembled plate having a non-detachable fastener would not be permitted. For example, a detachable fastener permits a surgeon to insert plate segments through a smaller incision in a patient as the plate can then be assembled within the wound. A detachable fastener permits a surgeon to select and combine plate segments of different sizes in order to more closely match the contour and size of the spinal segment of a particular patient. (See, e.g., '062 specification, page 9, lines 1-13). The bone rivet taught by McKinney is not "detachable" once applied. Therefore, an attempted use of the McKinney bone rivet with the invention defined by the claims of the '062 and '247 applications would not result in a fastener that is "detachably attached to at least one of the plate segments." Use of a fastener that is not detachable would eliminate the advantages identified above. Accordingly, Applicant submits that the subject matter of the '062 and '247 applications are each patentably distinct from the subject matter of the present application.

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

For the provisional obviousness-type double patenting rejection of the present application in view of the '062 application in particular, Applicant respectfully disagrees with the Examiner's contention that the '062 application teaches all the elements except for the fastener being non-detachably attached. Independent claim 1 of the '086 application, the only independent claim still pending in the '086 application, recites "at least one bone screw lock adapted to lock to said plate only a single bone screw inserted in one of said bone screw receiving holes." (Emphasis added). Neither the claims of the '062 application nor McKinney, whether alone or in proper combination, teach or suggest a bone screw lock adapted to lock at least two bone screws as recited in independent claims 1, 76, 118, and 183 of the present application. Accordingly, Applicant submits that this rejection is improper and must be withdrawn.

D. Double patenting in view of the '059 application.

For the Examiner's provisional obviousness-type double patenting rejection of the present application in view of the '059 application, Applicant respectfully disagrees with the Examiner's contention that "the invention of claims 1-143 of '059 application is in effect a "species" of the "generic" invention of claims 1-240 of '407 application." (Office Action, page 3, paragraph 3). Applicant submits that the relationship between the claims of the present application and those of the '059 application is the reverse of that stated by the Examiner, in that the claims of the present application are a "species" of the "generic" claims of the '059 application. However, this relationship of the claims may change after Applicant files a reply to the outstanding '059 Office Action.

(1) No Anticipation.

The Examiner further contends that the claims of the present application are "anticipated" by the claims of the '059 application. (Office Action, page 3, paragraph 3 to page 4, paragraph 1). In order to have "anticipation," the date of the anticipating reference must predate the earliest effective filing date of the claims against which the reference is being asserted. (See, e.g., MPEP § 706.02(a), page 700-22, col. 1, second paragraph (May 2004)). Applicant submits that anticipation does not exist between the

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

claims of the present application and the claims of the '059 application because both the present application and the '059 application were filed on June 4, 2002.

(2) Method claims moot.

In the '059 Office Action, in response to the restriction requirement, Applicant elected the claims directed to a plate adapted to be applied to the anterior human cervical spine. The Examiner of the '059 application withdrew the claims directed to the method. Applicant will cancel the method claims in reply to the '059 Office Action, thus rendering moot the provisional obviousness-type double patenting rejection of method claims 76-117 of the present application in view of the '059 application.

(3) Double patenting premature.

Moreover, Applicant submits that a determination of double patenting is premature at this time since the final scope of the claims of the '059 application has yet to be determined. According to the '059 Office Action, all the non-withdrawn claims of the '059 application are either rejected or objected to by the Examiner. Therefore, the final scope of the claims in the '059 application has not been determined. After the final scope of the claims of the '059 application is determined, Applicant will assess the need for a Terminal Disclaimer in view of the claims of the present application. In the meantime, Applicant respectfully requests the Examiner to withdraw the provisional rejection and permit the present application to proceed to issuance. Applicant submits that the provisional obviousness-type double patenting rejection is the only issue remaining in view of Applicant's remarks below with reference to the Examiner's art rejections. (See, MPEP § 804(I)(B), page 800-19, cols. 1 and 2 (February 2003)).

II. Rejections over the art of record.

The Examiner rejected claims 1-117 and 183-240 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,306,136 to Baccelli ("Baccelli") in view of McKinney and U.S. Patent No. 6,152,927 to Farris et al. ("Farris"). Applicant respectfully traverses the Examiner's rejection.

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

Applicant respectfully disagrees with the Examiner's contention that "Baccelli teaches all the elements, except for a fastener being non-detachably attached." (Office Action, page 6, paragraph 2). Baccelli fails to teach or suggest a fastener having "a first position adapted to facilitate movement of said first and second plate segments in a direction toward one another along the longitudinal axis of said plate and to resist movement of said first and said second plate segments in a direction away from one another along the longitudinal axis of said plate" as recited in independent claim 1. The screws 30 in Baccelli, when in a loose position, permit the plate segments to move both toward one another and away from one another. When in a "tightened position," the screws of Baccelli do not permit the plate segments to move relative to one another in either direction. (See Baccelli, col. 4, lines 4-10 and 37-40). There is no teaching or suggestion in Baccelli for a fastener having a position that "facilitates movement...toward" and "resists movement... away" of the plate segments along the longitudinal axis of the plate. Therefore, Baccelli does not teach all the elements of claim 1 "except for a fastener being non-detachably attached" as recited by the Examiner.

Applicant also respectfully disagrees with the Examiner's contention that "Baccelli discloses ... a lower surface being concave, as set forth in column 5, lines 1-8...." (Office Action, page 6, paragraph 1). The passage cited by the Examiner is directed to the inclination of the bone screws relative to the plate. (See, e.g., Baccelli, col. 5, lines 1-8). There is no mention of there being any concavity to the lower surface of the plate. The inclination of the bone screws can be achieved by forming the bone screw receiving holes at an angle to the plate and does not require the bottom surface of the plate to be concave. (See, e.g., Baccelli, Fig. 8). Moreover, as shown in Figures 2 and 3 of Baccelli, the bottom surface of the plate is flat, not concave. Therefore, the concave lower surface of the plate recited in independent claims 1, 76, and 183 is not taught or suggested by Baccelli as contended by the Examiner.

Application No. 10/180,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

Applicant respectfully submits that the combination of Baccelli, McKinney, and Farris is untenable and cannot be maintained at least for the reasons stated below.

A. The proposed modification renders the combination unsatisfactory for its intended purpose.

Applicant respectfully disagrees with the Examiner's contention that "it would have been obvious ... to replace the fastener of the '247 application with the fastener, as taught by McKinney...." (Office Action, page 6, paragraph 3). Applicant assumes that the reference to the '247 application was a typographical error by the Examiner as the claims of that application are not the subject of the present § 103(a) rejection. Baccelli teaches plate elements 10 that are held in position by two screws 30. (Baccelli, col. 4, lines 51-55; Fig. 1). McKinney teaches a rivet 11 having a head 33, a shank 25, and an inner head 49. (McKinney, col. 3, lines 40-43; col. 4, lines 43-45; and Fig. 1). The rivet is configured so that "the object 13 is clamped to the cortex 53 of the bone 17 by the two heads 33, 49 of the rivet." (McKinney, col. 4, lines 57-59; Fig. 1). The purpose of head 33 is to hold the plate while head 49 is "expanded against the cortex so as to secure the rivet means against the bone." (McKinney, col. 2, lines 15-17). Modifying the screws of Baccelli as taught by McKinney would render the Baccelli device unsatisfactory for its intended purpose because the bone rivet taught by McKinney is not adapted for securing two plate segments to one another. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)). Further, the bone rivet taught by McKinney is not configured to be subsequently tightened once a desired degree of compression is reached as taught by Baccelli (see Baccelli, col. 4, lines 51-55) and would thus not operate in a plate taught by Baccelli. (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)).

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

B. No motivation is used to support the combination of Baccelli with Farris and McKinney.

The Examiner contends that it would have been obvious "to modify the locking assembly of Baccelli, as taught by Farris et al., to have a bone screw lock capable of locking one or more bone screws within a respective screw hole " (Office Action, paragraph bridging pages 6 and 7). This statement does not provide any motivation as to why one would look to combine the teachings of Baccelli with Farris and McKinney. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Accordingly, Applicant submits that the rejection is improper and must be withdrawn.

Moreover, Applicant submits that modifying the assembly of Baccelli to have a locking element that is separate from the bone screw as taught by Farris would be redundant in view of the teaching of Baccelli. Baccelli teaches a bone screw with two different thread patterns, a first threaded part 21 to thread into the bone, and an intermediate thread 22 to engage the plate. Once the screws have been tightened, "the intermediate threads 22 are able to cooperate with the threads 1111 provided in the respective openings 111 to ensure that they are blocked at the root of the thread and thus to prevent their loosening" from the plate. (Baccelli, col. 3, lines 48-53 and col. 4, lines 41-45; Fig. 4). It would be redundant to add separate screw locks to bone screws that are already configured to prevent loosening from the plate. Thus, Applicant submits that there is no motivation to further add a bone screw lock to prevent loosening of the screws from the plate such as taught by Farris to the assembly taught by Baccelli when the bone screws in Baccelli are already configured to prevent loosening of the screws from the plate.

The Examiner also rejected claims 118-182 under 35 U.S.C. § 103(a) as being unpatentable over Baccelli in view of McKinney, Farris, and U.S. Patent No. 6,217,580 to Levin ("Levin"). Applicant respectfully traverses the Examiner's rejection. Applicant submits that the combination of Baccelli, McKinney, and Farris is untenable and cannot be maintained for the reasons stated above. Further, Applicant submits that the

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

combination of Baccelli, McKinney, Farris, and Levin is also untenable and cannot be maintained because the proposed combination still does not yield Applicant's claimed invention.

Independent claim 118 recites a plate system including "an instrument configured to cooperatively engage said fastener and at least a portion of at least one of said first and second plate segments so as upon movement of said fastener with said instrument said first and second plate segments move relative to one another along the longitudinal axis of said plate." Applicant submits that the combination of Baccelli, McKinney, Farris, and Levin does not teach or suggest an instrument configured to engage the fastener and at least a portion of at least one of the plate segments as claimed by Applicant. The Examiner's statement that "Levin evidences the use of an instrument that engages the first and second plate segments, and pull them close together" is irrelevant because this is not what is being claimed in claim 118. In claim 118, the instrument is configured to engage the fastener and at least a portion of one of the plate segments so that movement of the fastener with the instrument also moves the plate segments relative to one another. No such structure is taught or disclosed by Levin. Accordingly, Applicant submits that the rejection is improper and must be withdrawn.

Applicant submits that independent claims 1, 76, 118, and 183 are patentable over the art of record and that dependent claims 2-75, 77-117, 119-182, and 184-244 dependent from one of independent claims 1, 76, 118, and 183, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any

Application No. 10/160,407
Amendment dated September 13, 2004
Reply to Office Action of March 11, 2004

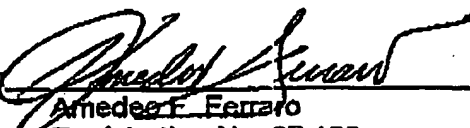
fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: September 13, 2004

By


Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030